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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,891	12/14/2006	Denise Faustman	00786/405004	1752
21559	7590			
CLARK & ELBING LLP				
101 FEDERAL STREET				
BOSTON, MA 02110				
EXAMINER				
BELYAVSKIY, MICHAEL A				
ART UNIT		PAPER NUMBER		
1644				
NOTIFICATION DATE		DELIVERY MODE		
07/15/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary

Application No.

10/577,891

Applicant(s)

FAUSTMAN, DENISE

Examiner

Michail A. Belyavskiy

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 146, 148-151 and 158-160 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 146 and 148-151 and 158-160 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date _____
- 6) ☐ Other: _____

RESPONSE TO APPLICANT'S AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/19/10 has been entered.

Claims 146 and 148-151 and 158-160 are pending.

Claims 146, 148-151 and 158-160 read on an isolated adult Hox11(+),CD45(-) cell are under consideration in the instant application.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 146, 148-151, 158-160 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection.**

“An isolated **adult cells**, wherein said cell expresses Hox 11” claimed in amended claim 146 represent(s) a departure from the specification and the claims as originally filed. The passages pointed by the applicant do not provide a clear support for “An isolated adult cells, wherein said cell expresses Hox 11”. Specifically, the paragraphs 0050, 0053 of the Specification only disclosed Hox-11 expressing pluripotent cells in the spleen of the adult mice. Moreover, the Specification explicitly disclosed that said cells as precursor pluripotent cells (see paragraphs 0013, 0016, 0058 etc).

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4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 146 and 148-151, 158-160 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent Application 2002/0187548 (IDS) for the same reasons set forth in the previous Office Action, mailed on 02/19/2010.

Applicant's arguments filed 05/19/2010 have been fully considered but have not been found convincing.

Applicant asserts that US Patent '548 does not disclosed adult Hox11(+) cells.

Contrary to Applicant's assertion, it is noted that US Patent'548 does not limited Hox11(+) to only embryonic cells. US Patent'548 explicitly teaches that the present invention relates to novel population of precursor Hox11(+) cells that are capable of developing into different cell types (see paragraph 0011, 0044 in particular).

Claims 148-151 are included because said structural properties would be an inherent properties of the recited cells expressing Hox 11. Since the office does not have a laboratory to test the reference isolated cells it is applicant's burden to show that the reference cells do not have the same structural properties as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

Claim 160 is included because the instant claims recited a product (an isolated Hox 11 expressing cells) and the patentability of the product does not depend on its method of production or source. *In re Thrope*, 227 USPQ 964,966 (Fed. Cir. 1985). See MPEP 2113.

The reference teaching anticipates the claimed invention.

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6. Claims 146 and 148-151, 158-160 are rejected under 35 U.S.C. 102(a) as being anticipated by Kodama et al. (Science, 2003, v.302, pages 1223-1227) or Ferrando et al., (Blood, 2002, v.100, n.11, page 154A).

Kodama et al., teach an isolated population of splenocyte, that lacks the expression of CD45 (see entire document, page 1224 and 1225 in particular). It is noted that Kodama et al., do not explicitly teach that said cells are Hox11(+). However, the reference and recited cells are the same isolated splenocyte as thus would inherently expressed Hox11(+). Since the office does not have a laboratory to test the reference isolated cells it is applicant's burden to show that the reference cells do not have the same structural properties as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

Ferrando et al., teach an isolated adult cell expressing Hox11 (see entire document. It is noted that Ferrando et al., do not explicitly teach that said cells are CD45- However, the reference and recited cells are the same as thus would inherently be CD45-. Since the office does not have a laboratory to test the reference isolated cells it is applicant's burden to show that the reference cells do not have the same structural properties as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

Claim 160 is included because the instant claims recited a product (an isolated Hox 11 expressing cells) and the patentability of the product does not depend on its method of production or source. *In re Thrope*, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113.

The reference teaching anticipates the claimed invention.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571/ 272-0735

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michail A Belyavskiy/
Primary Examiner, Art Unit 1644